AUG 3 0 2001

Summary Information

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K012593

1.	**Submitter name, address, contact**	Ortho-Clinical Diagnostics, Inc. 100 Indigo Creek Drive Rochester, New York 14626-5101 (716) 453-4041 Contact Person: Marlene A. Shulman
2.	**Preparation date**	Date Special 510(k) prepared: August 9, 2001
3.	**Device name**	Trade or Proprietary Name: VITROS Chemistry Products Magnetic HDL-Cholesterol Reagent VITROS CHOL Slide VITROS Chemistry Products Calibrator Kit 2 Common Name: HDLC Precipitating Reagent Classification Name: LDL & VLDL Precipitation, HDL
4.	**Predicate device**	The VITROS Chemistry Products Magnetic HDL-Cholesterol Reagent and VITROS CHOL Slides (modified) and VITROS Chemistry Products Calibrator Kit 2 are substantially equivalent to the VITROS Chemistry Products Magnetic HDL-Cholesterol Reagent and VITROS CHOL Slides (current slide) and VITROS Chemistry Products Calibrator Kit 2.

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7. Comparison to Predicate Device

The VITROS Chemistry Products Magnetic HDL-Cholesterol Reagent and VITROS CHOL Slides (modified) and VITROS Chemistry Products Calibrator Kit 2 are substantially equivalent to VITROS Chemistry Products Magnetic HDL-Cholesterol Reagent and VITROS CHOL Slides for use with human serum and plasma which was cleared by the FDA (K984303 January 28, 1999) for in vitro diagnostic use.

Table 1 lists the characteristics of the tests performed using the VITROS Magnetic HDL-Cholesterol Reagent and VITROS CHOL Slide (current) and the VITROS Magnetic HDL-Cholesterol Reagent and VITROS CHOL Slides (modified)

Table 1 List of Device Characteristics: Comparison to Predicate Device

Device Characteristic	Predicate Device **VITROS Magnetic HDL-Cholesterol Reagent and VITROS CHOL Slide (Current)**	New Device **VITROS Magnetic HDL-Cholesterol Reagent and VITROS CHOL Slide (Modified)**
Sample volume	10 µL	5.5 µL
Quantity of Reactive Ingredients per CHOL slide (test)	Triton X-100 0.91 mg; cholesterol oxidase (Nocardia or Cellulomonas, E.C.1.1.3.6) 0.45 U; cholesterol ester hydrolase (Candida rugosa or Pseudomonas, E.C.3.1.1.13) 2.25 U; peroxidase (horseradish root, E.C.1.11.1.7) 5.85 U; and 2-(3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis(4-dimethylaminophenyl) imidazole (leuco dye) 0.25 mg.	Triton X-100 0.73 mg; cholesterol oxidase (Nocardia or Cellulomonas, E.C.1.1.3.6) 0.36 U; cholesterol ester hydrolase (Candida rugosa or Pseudomonas, E.C.3.1.1.13) 1.80 U; peroxidase (horseradish root, E.C.1.11.1.7) 4.68 U; and 2-(3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis(4-dimethylaminophenyl) imidazole (leuco dye) 0.13 mg.
Intended Use	For in vitro diagnostic use only. The VITROS Magnetic HDL reagent and VITROS Cholesterol slides quantitatively measure HDL-cholesterol (HDLC) in serum and plasma.	No Change.
Concentrations of CHOL Reactive Ingredients per cm-squared	Triton X-100 0.81 mg; cholesterol oxidase (Nocardia or Cellulomonas, E.C.1.1.3.6) 0.4 U; cholesterol ester hydrolase (Candida rugosa or Pseudomonas, E.C.3.1.1.13) 2.0 U; peroxidase (horseradish root, E.C.1.11.1.7) 5.2 U; and 2-(3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis(4-dimethylaminophenyl) imidazole (leuco dye) 0.17 mg.	No Change.
Magnetic HDL-Cholesterol Reagent Reactive Ingredients.	Dextran sulfate (50,000 MW); Magnesium Chloride, Magnetically responsive particles.	No Change.

Device Characteristic	Predicate Device **VITROS Magnetic HDL-Cholesterol Reagent and VITROS CHOL Slide (Current)**	New Device **VITROS Magnetic HDL-Cholesterol Reagent and VITROS CHOL Slide (Modified)**
Basic principle	HDL is separated by precipitation of LDL and VLDL by using dextran sulfate (MW 50,000) and magnesium chloride. The reagent also contains iron particles that are coated with a polymer. The polymer enhances the precipitation of the non-HDL lipoproteins onto the iron particles. The precipitated non-HDL lipoproteins are removed from the supernate by applying a magnetic field. Following pretreatment of the sample, HDL cholesterol is measured by a dry, multilayered slide utilizing reflectance spectrophotometry	No Change.
Sample type	Serum , plasma	No Change.
Assay Range Serum, Plasma	3.0- 100.0 mg/dL	No Change.
Instrumentation	VITROS 250, 550, 750 and 950 Series Analyzers	No Change.
Incubation time and temperature	5 minutes at 37°C	No Change.

8. Conclusions

The information presented in this pre-market notification demonstrates that the performance of the VITROS HDL-Cholesterol Reagent and CHOL Slides (modified) for use with human serum and plasma is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using magnetic HDL-Cholesterol Reagent and manufactured slides along with patient and quality control samples with measured HDL-cholesterol values spanning the assay range.

The information presented in this premarket notification provide a reasonable assurance that the VITROS Magnetic HDL-Cholesterol Reagent and CHOL Slides (modified) for use with human serum and plasma is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 3 0 2001

Ms. Marlene A. Shulman
Regulatory Affairs Associate
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101

Re: K012593
Trade/Device Name: VITROS Chemistry Products Magnetic HDL-Cholesterol Reagent, VITROS CHOL Slide, and VITROS Chemistry Products Calibrator Kit 2
Regulation Number: 21 CFR 862.1150
Regulatory Class: II
Product Code: JIS
Regulation Number: 21 CFR 862.1475
Regulatory Class: I, reserved
Product Code: LBR
Dated: August 9, 2001
Received: August 10, 2001

Dear Mr. Shulman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K012593

Device Name:
VITROS Chemistry Products Magnetic HDL-Cholesterol Reagent
VITROS CHOL Slide
VITROS Chemistry Products Calibrator Kit 2

Intended Use:
For in vitro diagnostic use only.
The VITROS Magnetic HDL-Cholesterol Reagent and VITROS CHOL Slides quantitatively measure HDL cholesterol (HDLC) concentration in serum and plasma.

VITROS Calibrator Kit 2
For in vitro diagnostic use only.
VITROS Calibrator Kit 2 is intended for use in calibration of the VITROS Chemistry Systems for the quantitative measurement of CHOL, Cl-, ECO2, HDLC, K+, Na+, and TRIG.

Summary and Explanation of Test:
HDL cholesterol is used to evaluate the risk of developing coronary heart disease (CHD). The risk of CHD increases with lower HDL cholesterol concentrations.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Kevin Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012593